

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/039,957 03/16/98 KORNBLITH

P 2509-970451

HM22/0112

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EXAMINER

GITOMER, R

ART UNIT	PAPER NUMBER
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1623

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DATE MAILED:

01/12/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/039,957	Applicant(s) Kornblith
	Examiner Ralph Gitomer	Group Art Unit 1623

Responsive to communication(s) filed on Dec 4, 1900

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 25 and 27-36 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 25 and 27-36 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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The amendment received 12/4/00 have been entered and claims 25, 27-36 are currently pending in this application. The claims have been properly renumbered according to Rule 126 as new claims have been submitted. The dependencies are presumed to be consistent. It is noted a Terminal Disclaimer is mentioned but none has been received.

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In view of the newly submitted claims, the rejections of record under 102(b) and 112, first paragraph, are hereby withdrawn.

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It is understood the amended present claims are directed to hyperproliferative cells which includes malignant cells, whereas the claims of 08/679,056 and 09/095,993 are directed to malignant cells only. As the function of the methods are identical, the method steps are identical, and the only difference is the state of the cells in the assay, the following rejection is made under obviousness double patenting.

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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30 A timely filed terminal disclaimer in compliance with 37

CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

5 Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 25, 27-36 are provisionally rejected under the
10 judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of copending Application No. 09/095,993. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference in the claimed methods is the state
15 of the cells being malignant or non-malignant.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 25, 27-36 are rejected under the judicially created
20 doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 5,728,541. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference in the claimed methods is the state of the cells. The claims of
25 `541 are directed to malignant cells whereas the present claims are more broadly directed to cells in general.

Claims 25, 27-36 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5 In claim 33(e) sites are treated with treating means which is not related to chemosensitivity, no determining takes place before and after treating, and correlating chemosensitivity occurs which is not understood. The step of determining cell number is not understood in context. What the control is or
10 controls is not recited. More standard method steps include contacting, determining, correlating. In claim 34(e) what is correlated with what is not set forth.

15 The following prior art pertinent to applicant's disclosure is made of record and not relied upon:

Hoffman (Cancer and Metastasis Reviews) teaches 3D cultures.

20 Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist can be reached on (703) 308-1701. The fax phone number for this Art Unit is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1234. For 24 hour access to patent application information 7 days per week, or for filing

Serial No. 09/039,957
Art Unit 1623

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applications electronically, please visit our website at
www.uspto.gov and click on the button  Patent Electronic Business
Center  for more information.

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Ralph Gitomer
Primary Examiner
Group 1623

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**RALPH GITOMER
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